REMARKS/ARGUMENTS

Claims 1-17 are pending in the present application. No amendment is made to any of pending claims.

The Examiner rejected claims 1-17 under 35 U.S.C. 103 as being obvious over the combined disclosures of U.S. Patents 4,680,323 (the '323 Patent), 4,687,660 (the '660 Patent), and 6,033,686 (the '686 Patent).

The '323 Patent discloses a sustained release pharmaceutical carrier **comprising hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), and carboxyvinyl polymer**. As the '323 Patent states, **HPMC is a well known controlled release material** in pharmaceutical formulations (see col. 1, lines 34-45).

The '660 Patent discloses a pharmaceutical controlled delivery system for beneficial agents. The pharmaceutical delivery system comprises a core containing a beneficial agent, an osmotic enhancing agent, and a water-insoluble, water-permeable coating such as cellulose acetate surrounding the core. The beneficial agent can be bupropion hydrochloride.

The '686 Patent discloses a controlled release tablet comprising a core that contains bupropion hydrochloride and conventional excipients, and a coating that consists essentially of water-insoluble water-permeable film-forming polymer such as ethylcellulose. The '686 Patent discloses a method of preparing the composition comprising mixing the constituents and granulating with purified water.

Based on the above-mentioned references, the Examiner stated that a skilled artisan would have been motivated to combine the bupropion HCl of the '660 Patent into the formulation of the '323 Patent in order to impart stability and proper release of the agent. The Examiner further stated that a skilled artisan would have further been motivated to combine the purified water and additional excipients of the '686 Patent in order to better refine the processing and release profile of the active agent. Therefore, the Examiner rejected claims 1-17 as being obvious over the '323 Patent in view of the '660 Patent and further in view of the '686 Patent.

We respectfully traverse. It is our opinion that a *prima facie* case of obviousness has not been established. To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP §2143 -§2143.03 for decisions pertinent to each of these criteria.

In the present case, even if a skilled artisan had combined the bupropion HCl of the '660 Patent into the formulation of the '323 Patent, as the Examiner proposed, the formulation would comprise **bupripion HCl, HPMC, HPC, and carboxyvinyl polymer**. Hence, in addition to carboxyvinyl polymer, **at least HPMC would be a controlled release material in the proposed formulation,** which would be different from the formulation of the present invention, which comprises carboxyvinyl polymer as the sole controlled release material. Therefore, as Applicant stated in the response of September 22, 2003, **even if a person of ordinary skill in the art had made the combination as proposed by the Examiner, he or she would not have arrived at the present invention**.

Because the references when combined as the Examiner proposed do not teach or suggest all the claim limitations of the present invention, the Examiner failed to properly establish a *prima facie* case of obviousness. Further, **if the Examiner were to argue that the controlled release material other than carboxyvinyl polymer, for example HPMC, in the proposed formulation may be omitted to arrive at the present invention, Applicants should be informed of the motivation or suggestion, and a reasonable expectation of success for this omission, as required by U.S. law previously cited.** In fact, as MPEP 2144.04 (II.B) clearly instructs, the omission of an element and retention of its function is an indicia of

unobviousness. *In re Edge*, 359 F.2d 896, 149 USPQ (CCPA 1966). In the present case, the necessary controlled release material, HPMC, as described in the '323 patent, is omitted in the present invention, but the formulation in accordance with the present invention can still attain a desired controlled release profile (see e.g. page 5, lines 1-6 of the specification of the present application). This fact constitutes a ground that the present invention is unobvious over the references cited by the Examiner.

Moreover, as clearly stated by MPEP 2142, the examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. Therefore, it is our opinion that Applicants have no obligation to submit evidence showing the criticality of the present invention, as the Examiner proposed in the first paragraph of page 4 of the Office Action.

Based on the foregoing, Applicants believe that the claims of the present application are in condition of allowance. Early and favorable action is respectfully requested.

It is believed that no other fees or charges in addition to the one-month extension fee are required at this time in connection with the present application; however, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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